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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,829	12/01/2003	Mee Len Chye	V9661.0043	7267
32172	7590	11/18/2004	EXAMINER	
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 1177 AVENUE OF THE AMERICAS (6TH AVENUE) 41 ST FL. NEW YORK, NY 10036-2714			SAMSON, MARIA TERESA D	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/725,829

Applicant(s)

CHYE ET AL.

Examiner

Maria Teresa Samson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 8-47, and 49-58, drawn to isolated proteinase inhibitor II nucleic acid molecule, a method for producing a transformed plant, a transformed plant, a method for producing a heterologous protein in transgenic plants, and a method of use, classified in class 800, subclass 278.
- II. Claims 5-7, drawn to an isolated polypeptide having the amino acid sequence of SEQ ID NO:2 or 4, or a fragment of SEQ ID NO:2 or 4 having proteinase inhibitor activity, classified in class 530, subclass 350.
- III. Claim 48, drawn to a monoclonal antibody, classified in class 530, subclass 387.1.

2. The inventions are distinct from each other because:

Group I is independent and distinct from Groups II and III. The DNA molecule of Group I and the proteins of Group II and III are distinct because they are physically and functionally distinct chemical entities. The DNA molecule of Group I is made up of nucleotides while the proteins of Groups II and III are composed of amino acids. Furthermore, the DNA molecule may be used for processes other than the production of the protein of Group II or the fragment of the protein of Group II such as in nucleic acid hybridization assays and the protein of Group II can be made by another materially different process such as purification from the natural source. The DNA of Group I does not encode the antibody of Group III. The search requirement for protein and antibody

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involves both text and amino acid sequence searches while the search for DNA requires only a DNA sequence search. Therefore, the searches are not coextensive.

Groups II and III are independent and distinct from each other. The protein of Group II are related to the antibodies of Group III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities. In addition, the protein of Group II can be used in another materially different process, for example, inhibiting proteinases.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds that are unrelated to one another, as are different proteins are structurally distinct chemical compounds that are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Each sequence requires an independent search of the sequence databases. Absent evidence to the contrary, each such nucleotide is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq (see MPEP 803.04 and 2434).

Upon election of a Group, Applicant is additionally required to select a single nucleotide sequence and an amino acid sequence for said Group, as appropriate. This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of single genus of invention, but constitutes an independent and patentably distinct invention.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, subject matter and search requirement, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Teresa Samson whose telephone number is 571-272-3110. The examiner can normally be reached on 7:00-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

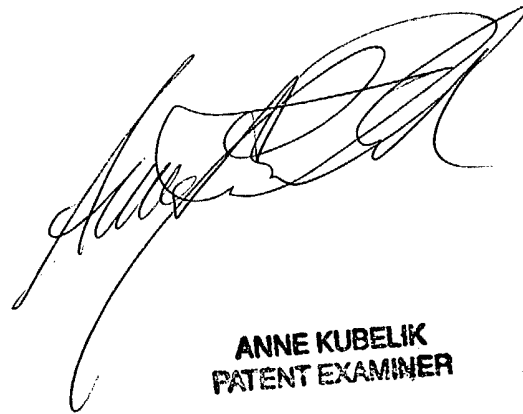
Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within

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5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Maria Teresa Samson, Ph.D

November 10, 2004



ANNE KUBELIK  
PATENT EXAMINER